JS 1/19/22
RJA 2/16/22

SAT Report for Case # P-18-0007

General

[redacted]

Report Status: Complete **Status Date:** 12/10/2018

CRSS Date: 10/12/2017 **SAT Date:** 10/13/2017 **SAT Chair:** D. Pagan-Rodriguez

Consolidated PMN? Y

Consolidated Set: P-18-0008

Submitter: Nexoleum USA Corp

CAS Number: 2097734-14-8

Ecotox Related Cases:

Health Related Cases:

Chemical Name: Glycerides, soya mono- and di-, epoxidized, acetates

Use: Plasticizer and stabilizer for flexible polyvinyl chloride (PVC) plastic.The substance is manufactured with epoxidized soybean oil (CASRN 8013-07-8, on TSCA) and epoxidized soya fatty acid methyl esters (CASRN 68082-35-9, on TSCA). Consolidated Se [redacted] P2REC: CRSS: forward. P2
Claims: The substance will be biodegradable, be a replacement for phthalate ester plasticizers, and have lower mammalian toxicity compared to the former.

Trade name: Nexo

PV Max (kg/yr): [redacted]

Ecotox Assessor: Kennedy, Amuel **Fate Assessor:** Placeholder, Legacy **Health Assessor:** Behrsing, Tracy

Physical Chemical Information

Molecular Weight:	470.81	**Physical State - Neat:**	Liquid		
Percent 500:		**Percent 1000:**			
Melting Point (Measured):		**Melting Point (est):**		**MPD (EPI):**	
Vapor Pressure:		**Vapor Pressure (est):**	<0.000001	**VP (EPI):**	
Water Solubility:		**Water Solubility (EST):**	0.00081	**Water Solubility (EPI):**	
Log Kow:				**Log Kow (EPI):**	
Log P:		**Log P Comment:**			

SAT Concern

Ecotox Rating (1):	1	**Ecotox Rating Comment (1):**	
Ecotox Rating (2):		**Ecotox Rating Comment (2):**	
Health Rating (1):	1-2	**Health Rating Comment (1):**	
Health Rating (2):		**Health Rating Comment (2):**	

PBT Ratings

Persistence	Bioaccumulation	Toxicity	Comments
3	1	1	

Exposure Based Review (Health)?	
Exposure Based Review (Ecotox)?	Y
SAT Keywords:	KIDNEY, LIVER, SENS, IRRIT

Fate Assessment Summary:	P-18-0007-08 FATE: Estimations for typical and low weight, MW = 471, C25H42O8 Liquid with MP < 25 °C (E) log Kow = 5.19 (E) S = 0.81 mg/L at 25 °C (E) VP < 1.0E-6 torr at 25 °C (E) BP > 400 °C (E) H < 1.00E-8 (E) log Koc = 4.54 (E) log Fish BCF = 1.72 (52) (E) log Fish BAF = 1.09 (12) (E) POTW removal (%) = 90 via sorption and biodeg Time for complete ultimate aerobic biodeg = wk Sorption to soils/sediments = moderate PBT Potential: P3B1 *CEB FATE: Migration to ground water = moderate Bioconcentration factor to be put into E-FAST: 12 PMN Material: Overall wastewater treatment removal is 90% based on sorption and biodegradation. Sorption to sludge is moderate to strong based on the estimated physical-chemical properties from EPISUITE. Air Stripping (Volatilization to air) is negligible based on the estimated physical-chemical properties from EPISUITE. Removal by biodegradation in wastewater treatment is high based on BIOWIN model

estimates and analogous chemicals.
The aerobic aquatic
biodegradation half-life is weeks based on BIOWIN model estimates and analogous chemicals.
The anaerobic aquatic biodegradation half-life
is greater than months based on the aerobic biodegradation half-life. The anaerobic biodegradation half-life is projected to be greater or equal to the aerobic biodegradation half-life.

Sorption to soil and sediment is moderate based on the estimated physical-chemical properties from EPISUITE.
Migration to groundwater
is moderate based on the estimated physical-chemical properties from EPISUITE.
PMN Material:
High Persistence (P3) is based on the
anaerobic biodegradation half-life.
Low Bioaccumulation potential
(B1) is based on BCFBAF model estimates.

Bioaconcentration/Bioaccumulation factor to be put into E-Fast:
12

Removal in WWT/POTW (Overall): 90

Condition	Rating Values w/ Rating Description	Comment
WWT/POTW Sorption:	2-3	
WWT/POTW Stripping:	4	
Biodegradation Removal:	2	
Biodegradation Destruction:		
Aerobic Biodeg Ult:	2	
Aerobic Biodeg Prim:		
Anaerobic Biodeg Ult:	4	
Anaerobic Biodeg Prim:		

Condition	Rating Values w/ Rating Description	Comment
Hydrolysis (t1/2 at pH 7,25C) A:		
Hydrolysis (t1/2 at pH 7,25C) B:		
Sorption to Soils/Sediments:	3	
Migration to Ground Water:	3	
Photolysis A, Direct:		
Photolysis B, Indirect:		
Atmospheric Ox A, OH:		
Atmospheric Ox B, O3:		

Health Assessment

Health Summary:	Absorption is poor through the skin, poor to nil through the lungs and poor through the GI tract (pchem). Concern for skin irritation based on info in SDS. Concern for kidney and liver effects based on analog data. Concern for sensitization for PMN components that are highly epoxidized (i.e., 5 epoxides per glyceride molecule). Low-moderate concern.
Routes of Exposure:	Dermal Drinking Water Inhalation

Test Data Submitted

Test Data Submitted:	Analog data can be found at OECD SIDS for Epoxidized oils and derivatives [redacted] and Human Health Form Part A

Ecotox Assessment

Test organism	Test Type	Test Endpoint	Predicted	Measured	Comments
Fish	96-h	LC50	*		* = no effects at saturation; Analog ECHA Dossier for CASRNs 68082-35-9, 68082-34-8, 61789-01-3, and 68082-35-9
Daphnid	48-h	LC50	*		* = no effects at saturation; Analog ECHA Dossier for CASRNs 68082-35-9, 68082-34-8, 61789-01-3, and 68082-35-9
Green Algae	96-h	EC50	*		* = no effects at saturation; Analog ECHA Dossier for CASRNs 68082-35-9, 68082-34-8, 61789-01-3, and 68082-35-9
Fish	-	Chronic Value	*		* = no effects at saturation; Based on analogs [redacted]
Daphnid	-	Chronic Value	*		* = no effects at saturation; Based on analogs [redacted]
Green Algae	-	Chronic Value	*		* = no effects at saturation; Based on analogs [redacted]

Factors	Most Sensitive Endpoint	Assessment Factor	CoC	Comment
Acute Acquatic:				Because hazards are not expected up to the water solubility limit, acute and

Factors	Most Sensitive Endpoint	Assessment Factor	CoC	Comment
				chronic concentrations of concern are not identified.
Chronic Acquatic:				Because hazards are not expected up to the water solubility limit, acute and chronic concentrations of concern are not identified.

Ecotox Route of Exposure?	No releases to water

Factors	Values	Comments
SARs:	Polyepoxides and Esters	
SAR Class:	Polyepoxide, Esters	
TSCA NCC Category?	Epoxides, Esters	

Recommended Testing

Ecotox
Value Comments

EPA estimated environmental hazard of this new chemical substance using hazard data on analogous chemicals (CASRNs 68082-35-9, 68082-34-8, 61789-01-3, and 68082-35-9; [redacted] MW 471; Log Kow = 5.19 (P, mono-fatty acid glyceride), 13.58 (P, di-fatty acid glyceride); liquid with an unknown MP (P); S = 0.81 mg/L (P, mono-fatty acid glyceride), 2.6E-9 mg/L (P, di-fatty acid glyceride) ; effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <150 mg/L as CaCO3; and TOC <2.0 mg/L.

Ecotox
Factors Comments

Environmental Hazard: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risk because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard of this new chemical substance using hazard

data on analogous chemicals (CASRNs 68082-35-9, 68082-34-8, 61789-01-3, and 68082-35-9; [redacted] Acute and chronic toxicity values estimated for fish, aquatic invertebrates, and algae are all no effects at saturation. These toxicity values indicate that the new chemical substance is expected to have a low environmental hazard. Because hazards are not expected up to the water solubility limit, acute and chronic concentrations of concern are not identified.

Environmental Risk: Risks to the environment from acute and chronic exposure are not expected at any concentration of the new chemical substance soluble in the water (i.e., no effects at saturation).